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NIXON PEABODY, LLP 300 S. Riverside Plaza 16th Floor CHICAGO, IL 60606			EXAMINER PREBILIC, PAUL B	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/237,605
Filing Date: January 25, 1999
Appellant(s): LAZZARA ET AL.

Elizabeth W. Baio
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 26, 2009 appealing from the Office action mailed October 21, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The decision rendered in this application on May 30, 2007.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

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US 5,571,017

NIZNICK

11-1996

Wennerberg et al "Design and Surface Characteristics of 13 Commercially Available Oral Implant Systems" The International Journal of Oral & Maxillofacial Implants, vol 8, no. 6 (1993), pp. 622-633.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 51 and 60-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki et al (the translation of Japanese patent JP3146679A2) or Wennerberg et al (Journal article entitled "Design and Surface Characteristics . . . ") in view of Niznick (US 5,571,017).

Haruyuki discloses an acid etched titanium implant surface with recesses having average depths of 0.5 to 5 microns; see the English language abstract and the "Technical Field" paragraph on page 2 and the "Effect" section on pages 3-4 of the translation. Haruyuki discloses making dental repair and biorepair members including bone fixation devices and artificial dental roots, but fails to disclose implants made with the macrofeatures of a head, a threaded portion and a lowermost end as claimed.

Likewise, Wennerberg discloses a wide variety of titanium implants with surface roughnesses known to the art including some with roughnesses under 10 micrometers; page 623, second column, fifth paragraph and page 624, Table 1, second column of numerical entries, "3I Miniplant, Ti" and "Nobelpharma" entries. Although Wennerberg discloses making screws and other implants, Wennerberg fails to disclose making the implant with macrofeatures of a head and a lowermost end as claimed.

However, Niznick teaches that it was known in the art to have different regions of roughness (where the roughened portion begins below surface (3) of Niznick), a tapered section (between (3) and (14) of Niznick or between sections (8) and (10) of Niznick), a smooth head portion (elements (2) and (3) of Niznick), a lowermost end (element (10) of Niznick) a roughened region that has a peak-to-valley roughness of less than 25 microns) and a self-tapping feature (element (8) of Niznick); see the abstract, Figure 1, column 2, lines 1-12, column 6, line 66 to column 7, line 24, column 4, lines 22-37, column 4, line 56 to column 5, line 6, and column 7, lines 9-24. Hence, it is the Examiner's position that it would have been obvious to have a smoother head portion, a threaded portion and a lowermost end in the Haruyuki invention for the same reasons that Niznick has the same.

With regard to the limitation pertaining to the minimum consumption of metal, the Examiner asserts that this process step would not affect the final surface property, and thus, the resultant product would be the same as one where there was a more than minimum consumption of metal; see MPEP 2113, which is incorporated herein by reference thereto.

With regard to claimed etching process steps that are considered to be product-by-process limitations, the Examiner posits that since a similar type of etching process is used to form irregularities on the surface of the same material as claimed that the surface irregularities of Haruyuki, that Haruyuki's surfaces would inherently be substantially the same as those set forth in the claims; i.e. cone-shaped and/or spaced about the prescribed distance.

Regarding claim 63 and the cone-shaped irregularities claimed, upon review of Exhibit 1 and Exhibit B, Comparative Example 2 of the Dr. Gubbi declaration filed June 30, 2003, the Examiner concluded that the prior art treatments do result in cone-shaped elements; see the artifact folder color micrographs of Exhibit A (3D surface map of Appellants' Osseotite) thereof and compare to the color micrographs of Exhibit A of Examples 2 to 5 (3D surface maps of surfaces treated according to Haruyuki's treatment process). Thus, this evidence is used as evidence that cone-shaped elements are inherently present on the surface of Haruyuki.

(10) Response to Argument

In response to the argument on page 13 if the brief that Haruyuki's surface is not inherently the same as the Appellant's surface, the Examiner asserts that Haruyuki's surface falls with the scope of the claims. After a review of the photographs filed with July 10, 2008, the Examiner notes that the photographs are of poor quality such that little detail can be ascertained therefrom. Furthermore, the claimed invention is broader than any particular example, and the surface disclosed as representing Haruyuki's surface falls within the claim scope.

With regard to Dr. Gubbi's declaration filed June 26, 2003, there is no document labeled Exhibit B filed along with that declaration or in any of the artifact files of this application. It may be that the photographs filed July 10, 2008 are intended to be the photographs referenced (in artifact filed 09237605ZB), but it is not seen how the present claims are clearly distinguishable from the samples called "Haruyuki actual photographs." The photographs of the Haruyuki translation are labeled "Photo 1", "Photo 2", etc. so it is not clear how that corresponds to the Appellant's use of "Figure 2" and "Figure 4."

Furthermore, Table B does not give peak to valley data so it is not clear how the Appellant and Dr. Gubbi can assert that there is a structural difference between the claimed invention and that of Haruyuki's samples.

On page 14 of the brief, the Appellant argues that Haruyuki teaches smoothening the surface on page 4 of the translation. The Examiner agrees but notes that the claim language is still met in that it requires peak to valley heights of not greater than 10 microns. Haruyuki also teaches that the mean pore size should be greater than 1 micron so that cell bonding not poor; see the "Effect" section on pages 3-4 of the translation.

Furthermore, Haruyuki explains that there is an optimum surface characteristic to obtain for cell adhesion and ongrowth. Acid treatment with a too strong acid (over 6% HF) leads to too large of pores sizes while a too weak acid (under 1% HF) leads to too small of pores sizes; see page 4, left column of the translation. "Smoothness" is not explicitly discussed. Rather, only rough edges and pores sizes are discussed.

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Furthermore, the fact that Haruyuki wants to optimize pores size and depth to promote cell attachment does not teach away from Niznick, but instead teaches a way of achieving what both references desire: cell attachment and ongrowth.

Next, the Appellant argues that the Appellant's surface appears different from Haruyuki's surface based upon the respective photographs. Again, the Examiner reiterates that the claimed product by process limitations are interpreted broadly and do not clearly result in a different structure from that disclosed by Haruyuki or Wennerberg. In particular, the Gubbi declaration failed to test the entire range of 1% to 6% HF, the entire range of 30 sec to 3 minutes, and the post treatment range of 1-6% HF, 1-10% H₂O₂, with the range of 10 to 60 seconds; see Table B located within Exhibit 8 or in artifact file 'ZB. Furthermore, the declaration failed to even set forth the peak to valley dimension of the samples.

On page 15 of the brief, the Appellant reiterates that the one page comparison of Exhibit 9 clearly shows the difference between Haruyuki and the presently claimed invention. However, the particular acid treatment utilized to make the photographed samples is not even set forth in the claims; the Board is requested to compare Gubbi declaration paragraph E with any of the three independent claims. For this reason, the Examiner reasserts that the surface features, as claimed, encompass the surface features set forth by Haruyuki or Wennerberg.

In section "2" of the brief, the Appellant asserts that Wennerberg does not disclose acid etched surfaces but rather discloses machined surfaces. In response, the Examiner asserts that the surfaces disclosed by Wennerberg meet the claim language

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pertaining to acid surfaces to the extent that such language can be given patentable weight.

In traversing the combination of Haruyuki or Wennerberg with Niznick (page 20 of the brief), the Appellant argues that Niznick teaches away because Niznick teaches the surface should be exceedingly rough. The Examiner asserts that Niznick was not used to teach particular roughnesses, but rather, that it was known to have different regions of roughness. In other words, Niznick does not teach away from the claimed invention because it merely utilizes different roughness criteria from that of Haruyuki or Wennerberg. Moreover, Haruyuki and Wennerberg provide evidence that the peak to valley dimensions of 10 microns or less were known for the purpose of cell attachment and ongrowth. Furthermore, “[t]he prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

In the middle of page 20 of the brief, the Appellant again argues that there is a teaching away because of different ranges of roughness. However, the Examiner reiterates that the threaded portion is the same as the Appellant's threaded portion as being 10 microns or less than 20 microns so it does not teach away by merely calling it something different.

The Examiner notes that analysis of the references does not match the actual language of the references; see page 8 of the response. In other words, the analysis has exaggerated the statements of the references. In particular, Haruyuki teaches that

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an average depth above 5 microns "**tends** to result in the appearance of sharp edges at the ridge lines between the depressions, which **can** cause tissue irritation" (emphasis added). Additionally, Niznick does not say that the roughness "must" be exceedingly rough as argued on page 8. The fact that Niznick teaches that certain areas of the implant are relatively rough does not constitute a teaching away.

Additionally, the Examiner asserts that since both references are concerned with rough surfaces for the purpose of ongrowth and ingrowth that the different dimensions alone do not make them incompatible. Disclosed embodiments or preferred embodiments do not constitute a teaching away; see MPEP 2123 (II) that is incorporated herein by reference.

The Applicant argues that Niznick teaches a different roughness than that claimed; see page 11 of the response. However, Niznick was not utilized to meet that limitation of the claim language. This argument is against the references individually. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With regard to Dr. Porter's Declaration, the claimed product-by-process steps are quite broad such that they are not commensurate in scope with the process steps used to make Applicant's samples; see the **First Test-Osseotite** on page 2 of the Dr. Gubbi's declaration filed June 30, 2003. From the description of the process, it is clear that very specific concentrations and treatment times were used that do not clearly exemplify a

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trend in the evidence; see MPEP 716.02(d) that is incorporated herein by reference.

For these reasons, the Examiner asserts that evidence does clearly does not support a conclusion of unobviousness.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided in this file. The Decision date was May 30, 2007.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Paul Prebilic/

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/Corrine M McDermott/

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